

Notice of Allowability

Application No.

10/701,870

Applicant(s)

SIEBER ET AL.

Examiner

Marsha M. Tsay

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to amendment received September 25, 2006.
2. ☒ The allowed claim(s) is/are 2,5-12,26-30,52,54 and 57.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1. <input type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____ |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date <u>10/30/06</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____ |

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Zhibin Ren on November 30, 2006.

The application has been amended as follows:

In the claims:

2. (currently amended) The ~~pharmaceutical~~ composition of claim 5, further comprising:

a carrier molecule that can be internalized by a living cell wherein the carrier molecule forms a conjugate with one or more Se(0) particles.

5. (currently amended) A ~~pharmaceutical~~ composition comprising:

elemental selenium (Se(0)) particles having a diameter of 0.4 to 1 nanometer; and a pharmaceutically acceptable delivering medium.

6. (currently amended) The ~~pharmaceutical~~ composition of claim 5, wherein the elemental selenium (Se(0)) particles can form a Se(0) colloid in a dispersion medium.

7. (currently amended) A ~~pharmaceutical~~ composition comprising:

elemental selenium (Se(0)) particles having a diameter of 0.4 to 1 nanometer;

a target cell-specific carrier molecule that can be internalized by a living cell wherein the carrier molecule forms a conjugate with one or more Se(0) particles; and

a pharmaceutically acceptable delivering medium.

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11. (currently amended) A ~~pharmaceutical~~ composition comprising:

elemental selenium (Se(0)) particles having a diameter of 0.4 to 1 nanometer;

a target cell-specific carrier molecule that can be internalized by a living target cell

selected from the group consisting of a cancer cell, an immune cell responsible for an autoimmune disorder, an alloreactive lymphocyte responsible for graft-versus-host disease or a rejection reaction, a parasite and a parasitized blood cell, wherein the carrier molecule forms a conjugate with one or more Se(0) particles; and

a pharmaceutically acceptable delivering medium.

52. (currently amended) A method for treating a human or nonhuman subject having cancer comprising the step of:

administering a composition that comprises a pharmaceutically effective amount of Se(0) particles having a diameter of 0.4 to 1 nanometers and a carrier molecule that can be internalized by a cancer cell, wherein the carrier molecule is albumin, and forms a conjugate with one or more Se(0) particles, to the human or non-human subject.

53. canceled.

55. canceled.

56. canceled.

57. (currently amended) A method for sensitizing a cell to a cytotoxic agent wherein the cell is resistant to the cytotoxic agent due to the presence of intracellular glutathione, the method comprising of:

treating the cell, or a human or nonhuman subject having the cell, with a composition that comprises Se(0) particles having a diameter of 0.4 to 1 nanometers and a carrier molecule that

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can be internalized by the cell and forms a conjugate with one or more Se(0) particles, wherein the cell becomes susceptible to the killing by an otherwise ineffective amount of the cytotoxic agent.

The following is an examiner's statement of reasons for allowance: claims 2, 5-12, 26-30, 52, 54, 57 are drawn to a method of making and using compositions comprising elemental selenium Se(0) particles. The elemental Se(0) particles have a diameter of 0.4 to 1 nanometer and are generated by exposing a photosensitizing selone dye to a suitable wavelength in the presence of molecular oxygen. The prior art (Zhang et al. 2001 Biofactors 15: 27-38) teach an elemental Se(0) particle between 20-60 nm, which is significantly larger than the 0.4 to 1 nanometer diameter of the instant invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Claims 2, 5-12, 26-30, 52, 54, 57 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Marsha M. Tsay whose telephone number is 571-272-2938. The examiner can normally be reached on M-F, 9:00am-5:00pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

December 4, 2006


KATHLEEN M. KERR, PH.D.
SUPERVISORY PATENT EXAMINER